

**REMARKS**

Claims 1, 3-5, 10, 12-13 and 16-23 are pending in the application and are under examination. Claim 1 has been amended for clarity. Claim 1 originally recited a mixture of gene and protein designations. The claim has been amended to clarify that it is the genes having the claim-recited expression characteristics. Applicant has therefore replaced the protein designations with their respective gene designations (*i.e.*, ICP0 and ICP4 were replaced with  $\alpha$ 0 and  $\alpha$ 4) for clarity. Claims 3 and 4 have been canceled. Claim 5 has been amended to reflect the amendment to claim 1. Claim 10 has been amended in an analogous manner. The limitations of claims 12 and 13 have been incorporated into claim 1, and thus these claims have been canceled as redundant over amended claims. Claim 22 has been amended in a manner analogous to claim 1, and to incorporate the limitation of treating *epidermal* cancer. Claim 24 has been added to define the HSV R7020 used in the method by reference to an HSV R7020 deposit. Support for claim 24 can be found in the specification-as-filed at page 6, lines 10-11. The amendments to the claims do not introduce new matter.

In the Office Action, claims 22 and 23 were again rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Claims 1-5, 10-12 and 16-23 were also rejected under 35 U.S.C. § 112, first paragraph, for assertedly lacking enablement commensurate in scope to the claims. Finally, claim 13 was subject to objection as being dependent upon a rejected base claim, although the Examiner acknowledged that it would be allowable if rewritten in independent form, including all of the limitations of the base claim and any intervening claims.

**Claim Rejection – 35 U.S.C. § 112, First Paragraph (Written Description)**

The Examiner rejected claims 22 and 23 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner further asserted that this was a new matter rejection, citing 37 C.F.R. § 1.118(a) as well as M.P.E.P. §§ 2163.02 and 2163.06. Specifically, the Examiner asserted that claims 22 and 23 encompass a method for treating a patient with a radiation-resistant cancer by administering a therapeutically effective amount of a HSV comprising a modification of an inverted repeat region such that only one  $\gamma$ 134.5 gene expresses an active gene product. The Examiner

characterized the claims as encompassing the treatment of any type of cancer that is radiation-resistant and using any HSV that comprises a modification of an inverted repeat region such that only one  $\gamma$ 34.5 gene expresses an active gene product. The Examiner asserted that the specification does not support the full scope of the claim. In a recent interview with Applicants' representatives, the Examiner acknowledged that the rejections of record would be obviated if the claims were amended to recite that the HSV is R7020 and the radiation-resistant cancer is radiation-resistant epidermal cancer. In response, Applicants disagree with the Examiner's assertions but have amended claims 1 and 22 to expedite prosecution.

Specifically, claim 22 has been amended herein to additionally recite the limitations of claims 12 and 13, as well as being amended to recite the treatment of epidermal cancer. Applicants submit that these amendments result in the claim being directed to treating radiation-resistant epidermal cancer using HSV R7020, which the Examiner has acknowledged is fully supported by the specification as originally filed (see Office Action at page 4, paragraphs 1 and 2). Applicants provide a declaration by inventor Roizman (Exhibit A) that confirms that claim 22 (as well as claim 1) defines HSV R7020. The declaration also establishes that HSV R7020 is identical to HSV NV1020. Thus, the claims have been amended to conform to the subject matter indicated to be allowable. Accordingly, Applicants submit that the rejection is moot and should be withdrawn.

#### **Claim Rejection – 35 U.S.C. § 112, First Paragraph (Enablement)**

The Examiner rejected claims 1-5, 10-12 and 16-23 under 35 U.S.C. § 112, first paragraph, for assertedly not enabling the full scope of the claims. Applicants acknowledge the Examiner's recognition that the methods of claims 1-2, 5, 10-11 and 16-21 (HSV is R7020), and the methods of claims 22-23 (cancer is radiation-resistant epidermal cancer and the HSV is R7020), are enabled. Applicants have canceled claims 3-4 and 12-13 herein, thus rendering moot the rejection of those claims.

Claims 1 and 22 have been amended herein to recite methods wherein the HSV is R7020 and, with respect to claim 22, wherein the cancer is radiation-resistant epidermal cancer. Specifically, because claim 1 already recites the deletion of  $\alpha$ 0, U<sub>L</sub>24 and

U<sub>1</sub>56, these genes were deleted from the group recited in claim 5 and 10 to avoid redundancy. As above, claims 1 and 22 have defined an HSV by its genotype, and that HSV is HSV R7020 (*i.e.*, HSV NV1020). Exhibit A is provided to confirm that the genotypes recited in claims 1 and 22 define HSV R7020. Accordingly, Applicants assert that the rejection of pending claims 1, 5, 10 and 16-23 has been obviated and the rejection should be withdrawn.

### **Claim Objection**

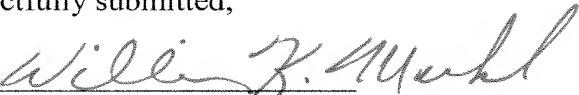
The Examiner objected to claim 13 for being dependent upon a rejected base claim and advised that it would be allowable if rewritten in independent form, including all of the limitations of the base claim and any intervening claims.

Applicants submit that claims 1 and 22 have been amended to incorporate the limitations of claim 13 and all intervening claims. Claim 13 has therefore been canceled herein, thus mooting the objection.

In view of the above amendments, Applicants submit that the pending application is in condition for allowance.

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Respectfully submitted,

By   
William K. Merkel

Registration No.: 40,725  
MARSHALL, GERSTEIN & BORUN LLP  
233 S. Wacker Drive  
6300 Sears Tower  
Chicago, Illinois 60606-6357  
(312) 474-6300  
Attorney for Applicant